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EXAMINER

KAM, CHIH MIN

ART UNIT PAPER NUMBER

1653

DATE MAILED: 01/07/2003

Lo

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/693,205

Applicant(s)

HUDSON ET AL.

Examiner

Chih-Min Kam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 October 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6-12 and 23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1, 9-12 and 23 is/are ~~allowed~~ *free of prior art*.
- 6) ☒ Claim(s) 2-4 and 6-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. Claims 1-4, 6-12 and 23 are pending.

Applicants' amendment filed October 22, 2002 (Paper No. 16) is acknowledged.

Applicants' response has been fully considered. Claims 1, 2, 6-8 and 23 have been amended, and claims 5, 13-22 and 24-29 have been cancelled. Thus, claims 1-4, 6-12 and 23 are examined.

2. Formal drawings filed November 21, 2002 (Paper No. 19) is acknowledged.
3. The substituted sequence listing and CRF filed October 22, 2002 have been entered.

Rejection Withdrawn

Claim Rejections - 35 USC § 112

4. The previous rejection of claims 1, 5-12 and 23, under 35 U.S.C.112, second paragraph, is withdrawn in view of applicants' cancellation of the claim, applicants' amendment to the claims, and applicants' response at pages 7-8 in Paper No. 16.

Claim Rejections - 35 USC § 102

5. The previous rejection of claim 6 under 35 U.S.C. 102(a) as being anticipated by Nagase *et al.* (DNA Research 5, 277-286 (October 1998)), is withdrawn in view of applicants' amendment to the claim, and applicants' response at page 8 in Paper No. 16.
6. The previous rejection of claims 2-3 under 35 U.S.C. 102(b) as being anticipated by Desseyn *et al.* (J. Biol. Chem. 272, 3168-3178 (1997)), is withdrawn in view of applicants' amendment to the claim, and applicants' response at pages 8-9 in Paper No. 16.

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7. The previous rejection of claim 6 under 35 U.S.C. 102(b) as being anticipated by Bouillaud *et al.* (Gene Bank Accession No. R17106, last updated June 12, 1996)), is withdrawn in view of applicants' amendment to the claim, and applicants' response at page 9 in Paper No. 16.

Informalities

8. The disclosure is objected to because of the following informalities:

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (page 42, lines 22-28). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

In response, applicants have amended the section containing the browser-executable code (pages 3-4 of the response), however, the amended section still contains part of the code, please delete the embedded hyperlink and/or other form of browser-executable code completely.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 2-4 and 6-8 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 2-4 and 6-8 are directed to a nucleic acid comprising an exon from a vertebrate gene wherein the exon is at least 12,793 base pairs; a fragment of SEQ ID NO:7 comprising

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nucleotide positions 6593 and 6594 of SEQ ID NO:7 and is at least 15 nucleotides; a nucleic acid comprising a nucleotide sequence, which has at least 60% sequence identity to SEQ ID NO:7 or a complement of SEQ ID NO:7; or a nucleic acid which hybridizes under stringency conditions to a nucleotide sequence comprising nucleotide positions 6593 and 6594 of SEQ ID NO:7 and is at least 10 flanking nucleotides of SEQ ID NO:7. The specification indicates that variants of the nucleic acid comprising an exon from a vertebrate gene, a spastin gene, a nucleotide sequence having at least 60% sequence identity to the claimed sequences such as SEQ ID NO:7, or a fragment of SEQ ID NO:7 (page 2, line 22-page 3, line 21; page 17, lines 5-10). However, the specification does not indicate a nucleic acid comprising an exon from a vertebrate gene and at least 12,793 base pairs contains SEQ ID NO:7. There is no disclosure indicating the nucleic acid having at least 60% sequence identity to SEQ ID NO:7 encodes a functional protein, or the fragment of SEQ ID NO:7 containing nucleotide positions 6593 and 6594 of SEQ ID NO:7 and at least 15 nucleotides in length is used as a probe. Without guidance on the identities of the nucleic acids which have 12,793 base pairs or at least 60% sequence identity to SEQ ID NO:7; or of fragments of SEQ ID NO:7 containing nucleotide positions 6593 and 6594, and at least 15 nucleotides in length; or of the nucleic acid that hybridizes under stringency conditions to a nucleotide sequence comprising nucleotide positions 6593 and 6594 of SEQ ID NO:7, and at least 10 flanking nucleotides in length, one skilled in the art would not know which nucleic acid molecule is identical to SEQ ID NO:7, which region of SEQ ID NO:7 is essential for coding a functional protein, or which fragments containing nucleotide positions 6593 and 6594 of SEQ ID NO:7 are used as probes. The lack of representative examples and teachings for the nucleic acid having 12,793 base pairs or at least 60% sequence identity to SEQ ID NO:7, or for the fragments

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of SEQ ID NO:7 containing nucleotide positions 6593 and 6594 as encompassed by the claims, applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise terms that a skilled artisan would not recognize applicants were in possession of the claimed invention.

In response, applicants indicate the claims have been amended to a nucleic acid comprising an exon from a vertebrate gene wherein the exon is at least 12,793 base pairs (claim 2), and claims 4, 6 and 8 have been amended such that a particular position of SEQ ID NO:7 (nt 6594) is indicated. The argument is not found persuasive because the specification does not indicate a nucleotide sequence from a vertebrate gene having at least 12,793 base pairs but without sequence identity contains SEQ ID NO:7, nor identify a nucleotide having at least 60% sequence identity to SEQ ID NO:7 and a fragment containing the particular position (nt 6594) as indicated in the section above.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

10. Claim 6 is rejected under 35 U.S.C. 102(a) as being anticipated by NCI-Cancer Genome Anatomy Project (CGAP, EST, January 04, 1999).

NCI-CGAP discloses a mRNA having 238 base pairs (AA897178), which contains, e.g., ttaatagctcctgcatatgt (corresponding to nucleotide position 6575 (1275+5300) to 6594

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(1294+5300), see sequence match result), with “g” at position 6593 and “t” at base 6594, and the polynucleotide has more than 15 nucleotides in length (claim 6).

Conclusions

11. Claims 2-4 and 6-8 are rejected, it appears claims 1, 9-12 and 23 are free of prior art.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, Ph. D. can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-4227 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. *CMK*
Patent Examiner

January 2, 2003

Christopher S. F. Low
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SUPERVISORY PATENT EXAMINER
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